

**REMARKS**

Claims 1-41 are pending, claims 1, 2, 4-15, 29-33 and 38-41 having been elected by applicants pursuant to the May 12, 2004 Response to Restriction/Election Requirement posed in this application and as acknowledged in item 1 of the August 19, 2004 Office Action. Claims 1, 4 and 29 are amended. Claims 12 and 13 are cancelled. Claims 42 and 43 are added. No new matter is submitted. Accordingly, entry of the Amendment is respectfully requested.

In item 2 of the Office Action, unspecified claims are indicated as withdrawn. Clarification of the specific claims intended to be withdrawn in item 2 of the Office Action is respectfully requested. For purposes of responding to the Office Action, Applicants presume that the withdrawn claims are 3, 16-28 and 34-37 pursuant to the May 12, 2004 election by Applicants. The withdrawal of claims 10-12 and 32 as indicated in item 3 of the Office Action is traversed by the Applicants immediately below.

In item 3 of the Office Action, elected claims 10-12 and 32 are indicated as withdrawn as allegedly drawn to a non-elected species. Applicants respectfully traverse this characterization of claims 10-12 and 32, and respectfully request rejoinder and continued examination of claims 10-11 and 32 within the elected Species I, as identified in the May 12, 2004 Response to Restriction/Election Requirement (noting that claim 12 is cancelled by this amendment). Claims 10-11 recite aligning means that pertain equally to the disk-shaped end-to-side anastomotic device body (106) of elected Species I (Figs. 1A-1C) as it does to the sleeve-shaped side-to-side anastomotic device body (106) of non-elected Species II (Figs. 3C), as set forth in the Specification at page 10, lines 17-21 and page 13, lines 13-15, for example. Likewise, the forming of the hole in the second vessel subsequent to attaching the second vessel to the body (106), as recited in claim 32, applies equally to Species I and Species II, as set forth in the Specification at page 12, lines 18-21, for example.

Accordingly, re-instatement of claims 10-11 and 32 for continued examination within elected Species I is respectfully requested.

In item 5 of the Office Action, claim 4 is objected to for recitation of “on between”. Claim 4 has been amended herein to delete the word “on” where indicated, thereby obviating the objection. Withdrawal of the objection to claim 4 is thus respectfully requested.

In item 6 of the Office Action, claims 1, 4, 5, 6, 9, 29-31, 33, 38, 39 and 41 are rejected under 35 U.S.C. 102(e) as allegedly anticipated by U.S. Patent Publication No. 2001/0001827 A1 to Chapman. The rejection is respectfully traversed.

To maintain a rejection under 35 U.S.C. 102 a reference must teach each and every element of a claimed invention. Chapman does not do so.

Applicants’ invention with respect to claims 1 and 29 comprises a device and method, respectively, for creating an anastomosis between first and second vessels using an extravascular body comprised at least partly from resorbable sponge material and secured to portions of a first vessel and a second vessel, the body having an opening or hole therethrough, such that fluid communication between the first vessel and the second vessel is achieved by the alignment of the first and second vessels with the opening or hole in the body.

U.S. Patent Publication No. 2001/0001827 to Chapman (hereafter “Chapman”) discloses an anastomosis device 8 and method for coupling a graft vessel with a target vessel. The device and method of Chapman specifies that a tubular member 20 is inserted intraluminally into both the graft vessel 10 and the target vessel 12 (paragraph [0035]). Moreover, Chapman discloses a radially compressible coupling member 30 overlying part of the tubular member 20 that is inserted into the target vessel 12 in order to anastomotically join the graft vessel 10 with the target vessel 12. Once inserted within the target vessel 12, the coupling member 30 radially expands to seal the graft vessel 10 against the inner walls of the

target vessel 12 (paragraph [0042]). Intraluminal blood flow necessarily contacts portions of the tubular member 20 or coupling member 30 of Chapman due to the intraluminal positioning of the tubular member 20 and coupling member 30 of Chapman. Further, nothing in Chapman teaches or suggests that the coupling member 30 is intended to be comprised even partly of a resorbable material. Nor would comprising the expandable coupling member 30 or tubular member 20 of a resorbable material be a reasonable alternative in Chapman, as such would tend to create leaks in the very anastomotic vascular junction that Chapman is intended to seal. Chapman thus fails to disclose either an extravascular or at least a partly resorbable body as recited in each of claims 1 and 29 of Applicants' invention. Chapman also fails to disclose anastomotically joining vessels with such an extravascular, partly resorbable body wherein blood flow through the joined vessels is achieved intraluminally, i.e., without contact of the body, as recited in new dependent claims 42 and 43. Accordingly, because Chapman fails to teach or disclose each and every feature of the claimed invention with respect to claim 1, from which claims 4, 5, 6, and 9 depend, and with respect to claim 29, from which claims 30, 31, 33, 38, 39, 41 depend, withdrawal of the 35 U.S.C. 102(e) rejection of claims 1, 4, 5, 6, 9, 29-31, 33, 38, 39 and 41 based on Chapman is respectfully requested.

In item 16 of the Office Action, claims 1, 2, 4, 5, 7, 8, 9, 14, 15, 29-31, 33, 38, 39 and 41 are rejected under 35 U.S.C. 102(b) as allegedly anticipated by U.S. Patent No. 6,117,147 to Simpson, et al. (hereafter "Simpson"). The rejection is respectfully traversed.

Applicants' invention with respect to claims 1 and 29, from which all of the other claims rejected based on Simpson depend, is discussed above.

Simpson discloses a device and method for reinforcing an anastomotic site and graft vessel. The device 14 and method of Simpson require a body 16 coupled to a sleeve 12 and a cuff 18. The device 14 and sleeve 12 receive the graft vessel (col. 3, lines 1-3 & 7-8),

whereas the cuff 18 engages the anastomotic site (col. 3, lines 13-16). In this manner, the graft vessel is directed to the target vessel, the body 16 and sleeve 12 reinforce the graft vessel, and the body 16 and cuff 18 reinforce the anastomotic site. The cuff 18 and body 16 are referred to as compressible to release medication contained therein (col. 3, lines 21-26 and col. 4, lines 1-4). Nothing in Simpson teaches or suggests that either the sleeve 12, body 16, or cuff 18 of the device 14 is comprised, wholly or partly, of a resorbable sponge material as recited in claims 1 and 29 of Applicants' invention. That Simpson fails to disclose even a partly resorbable body, is conceded in item 20 of the Office Action. Because Simpson fails to teach or disclose each and every feature of the claimed invention, withdrawal of the 35 U.S.C. 102(b) rejection of claims 1, 2, 4, 5, 7, 8, 9, 14, 15, 29-31, 33, 38, 39 and 41 based on Simpson is respectfully requested.

In item 20 of the Office Action, claim 13 is rejected as allegedly obvious under 35 U.S.C. 103(a) under Simpson in view of U.S. Patent Publication No. 2001/0044631 of Akins, et al. (hereafter "Akins"). The rejection is respectfully traversed.

The cancellation of claim 13 herein renders moot any rejection of claim 13. Accordingly, withdrawal of the 35 U.S.C. 103(a) rejection of claim 13 is respectfully requested.

To the extent that Akins is applied in combination with Simpson for suggesting the resorbable aspect of an anastomotic device, as alleged in item 20 of the Office Action, Applicants assert that the combination is misplaced as Applicants' invention comprises an extravascular, at least partly resorbable body for anastomotically joining first and second vessels together to provide fluid flow therethrough, as discussed above, whereas Simpson fails to disclose even a partly resorbable body, and Akins discloses a side-to-side and end-to-side device for connecting vessels but fails to disclose either an extravascular or a resorbable

body as the device. If the device of Akins were resorbable, then vascular obstruction would eventually occur at the anastomotic site, which is inapposite to the intended purpose, i.e., blood flow between vessels, of Akins. Moreover, the intraluminal device of Akins requires blood to directly contact portions of the device, whereas the method and device of the claimed invention provide intraluminal blood flow between vessels without direct contact of the blood with the at least partly resorbable body, notwithstanding the use of the extravascular body to achieve the anastomosis between the vessels.

In item 21 of the Office Action, claims 6 and 40 are rejected under 35 U.S.C. 103(a) as allegedly obvious over Chapman in view of U.S. Patent Publication No. 2001/0065545 to Leonhardt, et al. (hereafter “Leonhardt”). The rejection is respectfully traversed.

Applicants’ invention with respect to claims 1 and 29, from which claims 6 and 40 respectively depend, is discussed above. Likewise, Chapman is discussed above.

Leonhardt discloses an expandable vascular stent that is urged against an intraluminal vascular wall using a catheter balloon. This is considerably different than the securing means of Applicants’ invention wherein a catheter balloon is used to expand a vessel in order to urge an outer vessel surface to adhere to the extravascular resorbable body for creating an anastomosis between vessels. Leonhardt does not even apply to the anastomotic arts. Moreover, Leonhardt fails to overcome the deficiencies of Chapman with respect to the extravascular resorbable body. Thus, neither Chapman nor Leonhardt, alone or in combination teach, disclose or suggest the combination of features recited in claims 1 and 29, from which claims 6 and 40 depend. Accordingly, withdrawal of the 35 U.S.C. 103(a) rejection of claims 6 and 40 based on Chapman and Leonhardt is respectfully requested.

Applicants submit that the claims presented patentably distinguish over the art

applied. Accordingly, no 35 U.S.C. 112 issues existing, prompt allowance of the application in view of the remarks set forth herein is respectfully requested.

Should the Examiner determine that anything further is desirable to place this application in even better form for allowance, the Examiner is invited to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

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